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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,352	10/18/2007	Peter Kenneth Graham	1171/45540/172-PCT-US	7270
279	7590	11/04/2010		
CLARK HILL PLC 150 NORTH MICHIGAN AVENUE SUITE 2700 CHICAGO, IL 60601			EXAMINER LEE, SI M	
			ART UNIT 4123	PAPER NUMBER
			NOTIFICATION DATE 11/04/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mkitz@clarkhill.com

Office Action Summary	Application No. 10/599,352	Applicant(s) GRAHAM ET AL.	
	Examiner SI LEE	Art Unit 4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/30/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/26/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/26/06 and 8/30/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

STATUTES OF THE CLAIMS

Claims 1, 5, 8, 9, 11 were amended on 9/26/06 and 12-13 were cancelled on 9/26/06. Currently, claims 1-11 are pending for consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7, 8, 10, 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Carlsen et al. (7,549,419) herein after referred to as Carlsen.

Carlsen discloses a patient ventilating and aspirating system that they describe as a heat and moisture exchanger (HME) (20) adapter for a closed suction catheter assembly. The system comprises a pressurized source of gases which Carlsen describes as a HME (20) where it is intended to heat and moisturize the air in patients having artificial airways (column 1 lines 56-57). Carlsen discloses gases transport means adapted to convey the gases in use to the patient (column 1 lines 56-64); a patient connector (column 2 lines 18-20); a tracheostomy or endotracheal tube (column 2 lines 18-20); and patient connector adapted to be in fluid communication with gases transport means (column 2 lines 25-30, column 4 lines 65-66, and column 5 lines 1-3).

Carlsen (see figure 3) discloses a catheter mount (42) that is fitted in use between patient connector and gases transport means and includes an additional passageway for receiving an aspirating system (column 5 lines 57-64); Figure 7A illustrates the passageway that is covered by a seal (38) that includes a re-sealing mechanism (column 8 lines 65-68 and column 9 lines 1-5); a suction tube (60 that is surrounded by a collapsible envelope (62) (column 6 lines 5-6); The end is fitted with a connector and is moveable through a connector attached to the envelope with a suction means (column 6 lines 5-19); Figure 7A further illustrates a piercing member capable of piercing seal and capable of passing through piercing member and not contacting seal (38) (column 8 lines 61-67 and column 9 lines 1-19).

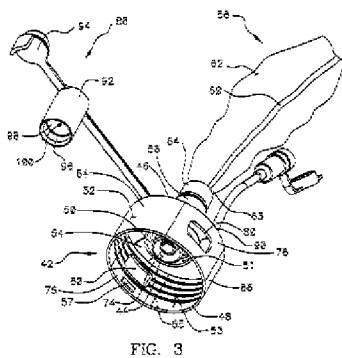


FIG. 3

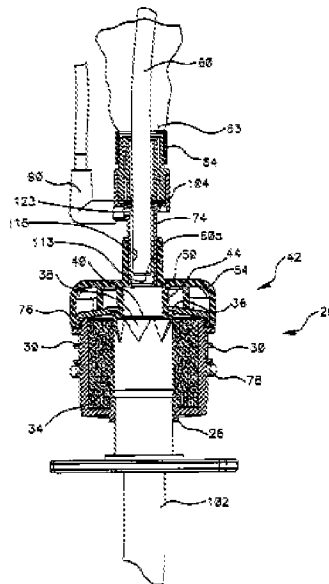
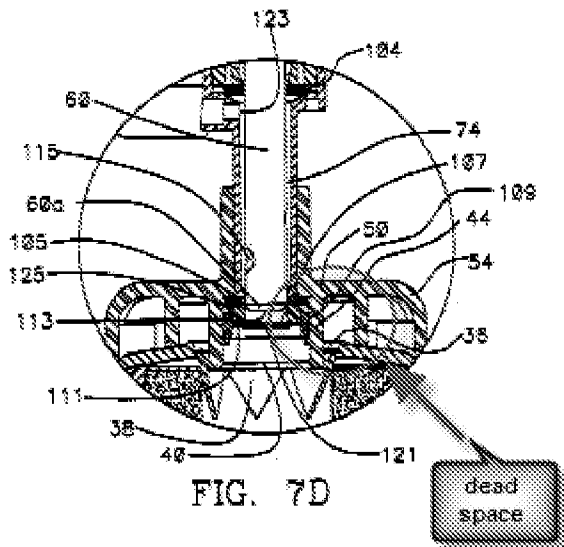


FIG. 7

Regarding claim 2, Carlsen figure 7D discloses a proximal connector is adapted to catheter mount (42) where a chamber is formed thereby creating a dead space therein.



Regarding claim 3, Carlsen discloses a proximal connector (46) and catheter mount (42) such that when connected, gases are prevented from leaking into chamber and exiting the atmosphere (column 5 lines 55-64 and column 9 lines 1-19).

Regarding claim 4, Carlsen discloses attachment of the adaptor to a closed suction catheter assembly (column 5 lines 55-64). Examiner interprets bayonet fitting as a fastening mechanism to connect/attach.

Regarding claim 7, Carlsen figure 7D shows dead space created and examiner contends that gases transport conduit that may leak through seal once pierced are enclosed and contained within. Carlsen discloses by keeping the projections (38) in the open position, the annular projection (44) allows the mucus to remain on the aspirating catheter until the aspirating catheter engages a seal.

Regarding claim 8, Carlsen discloses a catheter mount (42) that allows the passage of the suction tube (60) through the entry into the tracheostomy or

Art Unit: 4123

endotracheal fitting without the suction tube contacting the internal walls of the catheter mount (column 6 lines 5-14 and figure 7).

Regarding claims 10 and 11, Carlsen figure 7A and claims 15-17 (column 16) discloses all the features/elements of a suction tube and connector for connecting to a catheter mount. Carlsen figure 7D demonstrates a dead space formed when connector is connected to catheter mount and a chamber is formed.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlsen et al. (7,549,419) in view of Lorenzen et al. (5,715,815).

Regarding claim 5 and 6, Carlsen discloses a seal element but is silent on the seal's material. Although Carlsen is silent to the material composition, it appears from the specification and drawings that the seal is inherently resilient and flexible, as no additional hinge structure has been set forth. However, if not inherent, Lorenzen teaches the use of elastomeric material in a washer shaped wiping seal (400) (column 11 lines 46-48). Examiner contends that it would be obvious to one of ordinary skill in the art at the time of the invention was made to use an elastomeric material as obvious to try – choosing from a finite number of identified, predictable solutions, with a

Art Unit: 4123

reasonable expectation of success to use elastomeric material to provide a substantially airtight seal at normal operating pressures.

Regarding claim 6, Carlsen (see Figure 3 and 7A) discloses a seal with perforation (small hole) that allows the piercing of seal (38) by piercing member (column 8 lines 61-67 and column 9 lines 1-19). The passageway is re-sealed once connector is detached from catheter mount thereby prevents or reduces the prospects of contamination (column 9 lines 40-49).

Regarding claim 9, Carlsen discloses the components of the ventilating and aspirating system but is silent on a washer to wipe suction tube upon removal of tube from catheter mount. Lorenzen teaches washer (400) wipes any debris carried at the exterior surface of the catheter tube when the catheter tube is withdrawn from patient (column 11 lines 58-60). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention was made to apply a known technique to a known device ready for improvement to yield predictable results of clearing debris carried on the exterior surface of the tube upon removal from the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SI LEE whose telephone number is (571)270-5450. The examiner can normally be reached on Monday-Friday 7:30am-5pm.

Art Unit: 4123

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. L./
Examiner, Art Unit 3771
10.18.10

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774